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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,790	07/12/2000	Sharon F. Kleyne	HME/7982.001	2570
29085	7590	10/04/2004	EXAMINER	
HOWARD EISENBERG, ESQ. 2206 APPLEWOOD COURT PERKASIE, PA 18944			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/614,790

**Applicant(s)**

KLEYNE, SHARON F.

**Examiner**

Shengjun Wang

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 75-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2004 has been entered.

### *Claim Rejections 35 U.S.C. 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 75-89 are rejected under 35 U.S.C. 102(b) as being anticipated by a practice has been doing by many people, i.e., be in a mist environment, such as walking in a foggy morning, take a sauna bath. The claimed invention is directed to a method of moisturizing eye by contacting the surface of eye with less than 3 microliter (claims 75-82) or less than 10 microliter (claims 83-89). Any person step in a mist environment will subject his eyes to contact with the water mist. However, the amount of water absorbed on eye surface is not likely to exceed 3 microliter since the mist is not particularly directed to the eyes. Note, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are interpreted broadly as read on contact the eyes with mist. As to the functional limitation recited

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in claims 83 and 86, note, the functional limitation fails to distinguish the claimed method, since the ultimate steps in the method, i.e., contact eyes with mist, are not affected by such limitations. Further, note the size of droplets in mist is in the range of 2 to 100 micrometers. See "Selected terms in colloid and interface science Aerosols."

***Claim Rejections 35 U.S.C. 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 75-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Embleton et al (WO 97/23177) in view of Laibovitz et al (US Pat. 5,997,518).

Embleton teaches the advantages of administering smaller volumes of ophthalmic solutions to the eye. The tear volume can increase to about 30 microliters before overflowing occurs and the excess fluid is lost (see page 1, lines 5-23). Embleton also teaches that ocular bioavailability is enhanced by delivery to the eye in the form of a jet or stream of droplets (see page 2). As a general guide, Embleton teaches that droplet diameters in the range of 20 to 1000 microns are suitable, and that total volume should not exceed 20 microliters (see page 3, Lines 11-37). Ophthalmic treatment liquids may be aqueous, and optionally contain a therapeutic compound (see page 12, lines 6-9). Specifically named fluids include water, optionally containing polymeric compounds (see page 13, Lines 7-12). It is the position of the examiner that the optional ingredients are not required in the ophthalmic treatment liquids, and that Embleton specifically teaches the use of water as an ophthalmic treatment liquid.

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While the reference teaches the use of droplets with diameters generally in the range of 20-1000 microns and total volumes less than 20 microliters, the reference lacks teaching droplet diameter specifically in the 10-20 micron range and volumes in the 1-3 microliter range.

Laibovitz teaches a device and method for delivering small microliter volumes of liquid preparations to the eye. Laibovitz teaches that the ability of a system to deliver small volumes of a Liquid as droplets is of particular interest. The size of the drop is as found in an aerosol or mist, in the 1-5 micron range (see col. 3, Lines 11-27). Laibovitz teaches that the smaller volumes are especially designed to remain within the capacity of the eye to hold the solutions (see col. 3, Lines 35-40). The apparatus as taught by Laibovitz delivers small volumes between 1 and 25 microliters (see col. 5, lines 8-14). Tables 1 and 2 show delivery of 2 microliters of fluid by the device as taught by Laibovitz (see col. 13, Line 19 through col. 15, line 40).

It would have been obvious to one of ordinary skill at the time the invention was made to have modified the administration of compositions as taught by Embleton by the use of the methods and apparatus as taught by Laibovitz in order to avoid overflowing the capacity of the tear film and subsequent loss of the administered fluid.

As to the functional limitation recited in claims 83 and 86, note, the functional limitation fails to distinguish the claimed method, since the ultimate steps in the method, i.e., contact eyes with mist, are not affected by such limitations.

### ***Response to the Arguments***

Applicants' amendments, remarks, and the three declarations and the exhibit have been fully considered, but are not persuasive for reasons discussed below.

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6. The declarations under 37 CFR 1.132 filed February 2, 2004 is insufficient to overcome the rejection of claims 75-82 based upon Embleton et al (WO 97/23177) in view of Laibovitz et al (US Pat. 5,997,518) as set forth in the last Office action because:

A) It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. E.g., the claimed invention is directed to moisturizing eye in general, not limited to treat patient suffering from dry eye or other eye disorders, and is in need of the relief of the eye symptom by using the particular package or apparatus. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

B) The declarations ignore the teachings of the cited references, e.g., liquid should be in small amounts as disclosed by Embleton. One of ordinary skill in the art would have not expected such small amount of water would result in deleterious effect.

C) the declaration compared a commercial product, not the teaching of the cited prior art.

Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be *commensurate in the scope with any evidence of unexpected results*. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.132 must compare *the claimed subject matter* with the *closest prior art* in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (e).

7. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

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Applicants argue that no prima facie case of obviousness has been established. Particularly, applicants assert again that stream of droplets as disclosed by Embleton is not a mist. As presented early by applicants, mist is defined, (as commonly accepted by ordinary skill in the art): "a cloudlike aggregation of minute globules of water suspended in the atmosphere at or near the earth's surface, reducing visibility to a lesser degree than fog. 2. a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief.* . (emphasis in the original)." The examiner fails to see the difference between the "mist" and the stream of droplet disclosed by Embleton. They are both a mass of droplets dispersed in air. Applicants' recitation of Laibovitz (US Patent 5,997,518) is not found at column 14, line 20-25, no in anywhere else in Laibovitz. Clarification is encouraged.

Applicants further argue, even if a prima facie case of obviousness has been established, it would be successfully rebutted by the evidence presented in the declarations of Dr. Philip Paden, Dr. Darwin Liao, and Dr. William Mathers, and in Exchange & commissary News, 43 (1):6 (January 15, 2004). As discussed above, the declarations, as well as the exhibit, fails to rebut the prima facie of obviousness.

Applicants allege that the declaration of Dr, Philip Paden provides evidence of proceeding contrary to accepted wisdom. The examiner disagrees. Particularly, the declaration or applicant fails to consider the teaching of cited references. As discussed in the rejections, the claimed method would have been obvious over the cited reference. Therefore, the examiner do not see the achieved results shown by the exhibit provide any contrary to the teaching of cited references.

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As to the assertion of unexpected results base on the declarations by Dr. Liao and Dr. Mathers, note regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be *commensurate in the scope with any evidence of unexpected results*. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.132 must compare *the claimed subject* matter with the *closest prior art* in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e).

With respect to Exchange & commissary News, 43 (1):6 (January 15, 2004), which affirm that the claimed invention functions as it intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See, MPEP 716.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR




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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**SHENGJUN WANG**  
**PRIMARY EXAMINER**

Shengjun Wang  
Primary Examiner  
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